

### REMARKS

Claims 26-38 are pending. Claim 26 is the only independent claim.

Claim 26 has been amended for clarification. In particular, we have amended the claim to recite that the balloon in the medical balloon catheter is inflatably expandable.

Prior to this response, all of the claims were rejected as unpatentable over Zdrahala (U.S. 5,248,305). The rejection reasons that: "Zdrahala teaches an extruded catheter and other flexible plastic tubing manufactured from a liquid crystal polymer (LCP)," (Office Action page 2) and "[a]lthough Zdrahala fails to expressly teach a balloon, it is the Examiner's position that a balloon configured to be attached to a catheter would be included in the teaching of 'extruded catheters and *other flexible plastic tubing*'" (Office Action page 3, citing Zdrahala at col. 1, line 9).

Applicants traverse. The reasoning is clearly improper. An inflatable balloon, as applicants claim, would not be suggested by Zdrahala. Inflatable balloons and flexible tubing of Zdrahala type are different structures, with different functions, and, as a result, different design considerations. The Zdrahala reference itself illustrates this.

The key to Zdrahala is a tubing that can be urged through a blood vessel by twisting and pushing one end. For this rotational stiffness is important. Zdrahala states:

"Extruded catheters and other flexible plastic tubing may, in many circumstances, require a greater degree of torsional or rotational stiffness than is normally provided by a conventional plastic material ... For example, intravascular catheters for heart catheterization or PCTA need to be guided through the branching network of the patient's arterial system." (col. 1, lines 17-20, emphasis added)

"Typically, such catheters may be 'steered,' in which the physician rotates the catheter, which may have a bent tip, to select a path when a blood vessel junction is encountered. For such a catheter, it is highly desirable to exhibit good rotational stiffness in addition to axial stiffness." (Col. 1, lines 20-25, emphasis added)

As a result, Zdrahala adds LCP to his tubing to improve rotational stiffness:

"By this invention, catheters and other tubing may be provided which do exhibit improved rotational stiffness by themselves, without the support provided by a braided wire sleeve or the like." (Col. 1, lines 60-62, emphasis added)

An inflatably expandable balloon for a medical balloon catheter, on the other hand, must be inflatably expandable, typically to high pressures with low radial expansion (see, e.g., applicants' specification at page 1, lines 23-26). Also, it is typically collapsible so that the balloon can be deflated to a small profile for removal from the patient. Not only is rotational stiffness not a desired attribute, too much stiffness can inhibit deflation or cause abrasion.

Indeed, it is telling that, noticeably absent from Zdrahala is any reference to an inflatable balloon, even though he clearly identifies the application of his LCP catheters to angioplasty procedures (e.g., PTCA) where such balloons are crucial (see, e.g., col. 1, lines 17-20, shown above). Thus, Zdrahala is exemplary of one for whom it is not obvious that an LCP extruded layer that improves rotational stiffness in catheter is useful in an inflatably expandable balloon configured for attachment to such a catheter. Accordingly, we ask the Examiner to withdraw the obviousness rejection under Section 103.

We acknowledge the obviousness-type double patenting rejections over claims in U.S. Patent No. 5,270,086 and U.S. Patent Application No. 08/907,170. We intend to file an appropriate terminal disclaimer upon an indication that the claims are otherwise patentable.

Applicant : Robert N. Hamlin  
Serial No. : 09/557,473  
Filed : April 24, 2000  
Page : 4

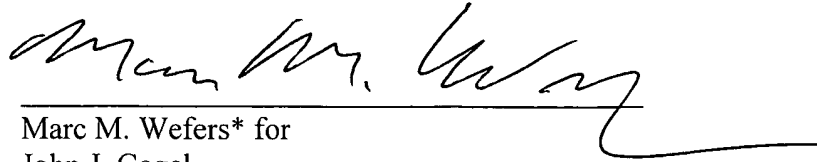
Attorney's Docket No.: 10527-003007 / PC7558F-US

Notwithstanding the double patenting rejections, we submit that all of the claims are now in condition for allowance, which action is requested. Filed herewith is a Petition for Automatic Extension with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

2/23/01

  
\_\_\_\_\_  
Marc M. Wefers\* for  
John J. Gagel  
Reg. No. 33,499

Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110-2804  
Telephone: (617) 542-5070  
Facsimile: (617) 542-8906

**\*See attached document certifying that Marc M. Wefers has limited recognition to practice before the U.S. Patent and Trademark Office under 37 C.F.R. § 10.9(b).**